REMARKS

Favorable entry and reconsideration of this application is respectfully requested.

Claims 1, 3-6, 8-11 and 14, 15, 19-24 are pending in this application. Claims 19-23 are deemed withdrawn.

Before addressing the Examiner's rejections, Applicant wishes to respectfully address the Examiner's Response to Applicant's Arguments listed on page 2 of the Final Office Action mailed March 11, 2011, wherein the Examiner states that Scetbon clearly discloses a hydrophilic absorbable material on the support to form at least one protected zone and at least one non-protected zone. Applicant respectfully disagrees.

As described in the present application, a protected zone is a portion of a mesh wherein the microporous structure of the mesh is occluded and a non-protected zone is a portion of a mesh wherein the microporous structure of the mesh is not occluded. Since Scetbon fails to disclose that the film occludes the microporous structure of the Scetbon tape, Scetbon also fails to disclose that the tape includes a protected zone and/or a non-protected zone. Thus, Scetbon can not be said to disclose a support with a protected zone and a non-protected zone as applied to the present application. Thus, any rejection which includes Scetbon should be withdrawn.

Turning now to the rejections, claims 1, 3-6, 8-10, and 14, 15, and 24 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,042,592 to Schmitt (hereinafter "Schmitt") in view of U.S. Patent No. 6,638,312 to Plouhar et al. (hereinafter "Plouhar") and U.S. Patent No. 6,406,423 to Scetbon (hereinafter "Scetbon"). This rejection is respectfully traversed.

Applicant respectfully maintains that the Examiner has failed to meet his burden in providing a *prima facie* case of obviousness. In accordance with M.P.E.P. §2145, an

obviousness rejection under 35 U.S.C. §103 may be rebutted by showing that the cited references teach away from their combination. More specifically, Applicant maintains that the combination of Schmitt and Scetbon is improper because the references teach away from their combination.

Schmitt discloses a soft and pliable multifilament surgical support mesh, wherein the interstitial voids located between the filaments are completely enclosed within a continuous (with respect to the microporous structure) infection impervious matrix. Scetbon discloses a tape made from a polypropylene monofilament mesh which includes a film positioned on a central portion of the mesh only. Schmitt teaches away from using a monofilament and specifically a polypropylene monofilament, to form the mesh of Schmitt. Schmitt also teaches away from positioning a matrix or film to cover only a central portion of mesh.

Initially, Scetbon discloses a tape made of a wide mesh monofilament polypropylene, which includes a re-absorbable hydrophilic film in its central portion which reduces the risk of erosion or sclerosis of the urethra. More particularly, at column 3, line 65 through column 4, line 6, Scetbon discloses the following:

> The tape is constituted by a knitted macroporous material, for example a wide mesh monofilament polypropylene. The tape is between 10 and 14 mm wide; it is 30 to 50 cm long, preferably about 40 cm.
>
> Tape 21 can have a re-absorbable hydrophilic film in its central portion which reduces the risk of erosion or sclerosis of the urethra to a minimum. This central zone is indicated by a coloured marker.

Nowhere is the re-absorbable film of Scetbon disclosed as occluding the microporous structure and/or the macroporous structure of the Scetbon tape. Rather, Scetbon discloses that the re-absorbable film is only positioned on the central portion of the tape and the tape is made of polypropylene monofilaments.

Turning now to Schmitt, the Background of the Invention of Schmitt implies that prior art monofilament meshes, and particularly polypropylene monofilament meshes, require improvement because surgical mesh formed from monofilaments are stiff and have limited pliability or flexibility. Schmitt further implies that multifilament meshes are softer and more pliable in comparison to monofilament meshes. More specifically, Schmitt states the following:

> Surgical mesh may be produced by knitting, weaving, braiding, or otherwise forming a plurality of yarns into a support trellis. Moreover, such mesh may be produced with monofilament or multifilament yarns made of materials such as polypropylene and polyester. Surgical mesh formed of monofilament yarn provides satisfactory reinforcement ability, but is generally stiff and has limited pliability. In contrast, surgical mesh formed of multifilament yarn is soft and pliable in comparison to mesh formed of monofilament yarn. (column 1, lines 18-27) (Emphasis added.)
>
> An example of a prior art surgical mesh is disclosed in U.S. Pat. No. 2,671,444. The surgical mesh described therein is an integral network of interconnecting yarns formed by molding a polyethylene resin. In essence, the '444 mesh is a molded, monofilament mesh and, hence, is relatively stiff and exhibits limited pliability. (column 1, lines 36-41) (Emphasis added.)
>
> U.S. Pat. No. 3,054,406 discloses another example of a surgical mesh used for repair and restoration of living tissue. The surgical mesh described therein may be woven from either monofilament or multifilament polyethylene yarns. The mesh has limited pliability when formed of monofilament yarns, and may be prone to harboring of infectious matter when formed of multifilament yarns. (column 1, lines 42-49) (Emphasis added.)
>
> U.S. Pat. No. 4,452,245 discloses still another example of a surgical mesh. The surgical mesh described therein is formed with monofilament polypropylene yarns which are knitted into a continuous tubular shape. The knitted mesh is porous and exhibits infection-resistant characteristics because of its monofilament construction. However, the monofilament mesh tends to be stiff and relatively non-pliable, which detracts from the body's ability to incorporate the mesh. (column 1, lines 50-58) (Emphasis added.)

Clearly, the Background of Schmitt attempts to differentiate his multifilament surgical mesh from the prior art monofilament mesh, specifically polypropylene, based on the softness and/or pliability of the mesh. Schmitt seeks to propose an alternative to monofilament mesh to avoid these perceived flexibility issues. Thus, Schmitt teaches away from the use of monofilaments, and particularly polypropylene monofilaments, to form a surgical support mesh.

In addition, Schmitt discloses a film which completely envelops the arrangement of multifilaments thereby occluding the microporous structure or interstitial voids between the multifilaments without covering the macroporous structure of the Schmitt mesh. Thus the microporous structure of the entire Schmitt mesh is occluded and the macroporous structure of the entire mesh of Schmitt is not occluded or remains open. Therefore, Schmitt does not disclose a non-continuous film with respect to the microporous structure of the mesh, but rather discloses a continuous film with respect to the microporous structure of the mesh, wherein the film completely encapsulates the arrangement of multifilament threads while also maintaining the macroporous structure of the Schmitt mesh. More specifically, at column 4, line 49- column 5, line 7, Schmitt discloses the following:

> Particularly, the matrix, which completely encloses the interstitial voids between the filaments of the yarn, provides an effective barrier to the passage of infectious matter between the interior and exterior of the yarn. Accordingly, any voids remaining in the yarn after encapsulation of such yarn are enclosed (and thereby sealed) within the resultant matrix. (Emphasis added.)
>
> A first embodiment of the present invention is shown in FIG. 2. Particularly, this first embodiment includes a support trellis 20 formed of multifilament yarns 22 and 24 which overlap at cross-over junctions 25. Subsequent to forming of the trellis, such trellis is encapsulated within a matrix 26, which is preferably a flexible material that continuously surrounds the exterior of the yarns thereby enclosing interstitial voids 27 located between filaments 28 (see FIG. 2a). In one embodiment, the

> matrix is formed from a polymeric resin. (Emphasis added.)
>
> As shown in FIG. 2a, the resin can be applied to the yarn in such a manner as to not allow the resin to substantially penetrate into the yarn. Particularly, the penetration of the resin can be controlled through the application procedure, e.g., quantity of resin applied and/or encapsulating time. In such an embodiment, the interstitial spaces are enclosed (rather than filled) within the continuous matrix. However, it is contemplated that the resin can be allowed to penetrate into the yarn, thereby substantially filling the void space located therein. (Emphasis added.)

Thus, according to Schmitt, the film completely encloses the interstitial voids between the multifilaments of the yarn, and any voids remaining in the yarn after encapsulation of such yarn are enclosed (and thereby sealed) within the resultant matrix. By stating the film completely encloses the interstitial voids and that any remaining voids are also encapsulated or enclosed, Schmitt clearly teaches away from placing a film or matrix on only a central portion of the mesh.

In providing substantial advantages of his multifilament meshes over prior art monofilament meshes, particularly made from polypropylene monofilaments, such as those disclosed in Scetbon, Schmitt effectively teaches away from Scetbon. Thus, the combination of Schmitt in view of Scetbon is improper and insufficient to support a *prima facie* case of obviousness against any of claims 1, 3-6, 8-11, 14, 15, and 24.

Although Applicants maintain that the Examiner has failed to properly meet his burden of proof regarding a *prima facie* case of obviousness, Applicants wish to address the Examiner's rejections further in an effort to further expedite the processing of the present application. Applicants respectfully submit that Schmitt, Plouhar and Scetbon, alone or in any combination, fail to teach or suggest the claimed medical device.

Nowhere does Schmitt disclose a textile support having a protected zone wherein the microporous texture of the support is occluded and a nonprotected zone wherein the microporous

texture of the support is not occluded. Rather, Schmitt discloses a mesh wherein the entire microporous texture is occluded, i.e., a protected zone. Thus the mesh of Schmitt fails to include a nonprotected zone or a portion in which the microporous structure of the Schmitt mesh is not occluded. Since, the microporous texture of the entire Schmitt mesh is occluded, no portion of Schmitt is nonprotected.

In addition, no portion of the macroporous texture of the Schmitt mesh is occluded. Thus, Schmitt also fails to disclose a textile having a protected zone wherein a portion of the macroporous texture is occluded and a portion of the macroporous texture is not occluded. Thus, Schmitt fails to render obvious the claimed composite prosthesis.

Plouhar fails to remedy the deficiencies of Schmitt. Nowhere does Plouhar disclose a textile support having a protected zone wherein the microporous texture of the support is occluded and an unprotected zone wherein the microporous texture of the support is not occluded. In fact, the Examiner specifically states that Plouhar discloses a prosthesis with a macroporous structure and fails to describe Plouhar with reference to a microporous structure. Rather, Plouhar discloses a mesh wherein the macroporous texture of the mesh may or may not be occluded. In Plouhar, either the macroporous texture of the mesh is coated or it is not, but there is no disclosure of occluding the microporous texture of any portion of Plouhar. In fact, Plouhar fails to even recognize that the mesh of Plouhar may include a microporous texture.

Thus, like Schmitt, Plouhar fails to disclose a textile support that has a protected zone wherein the microporous texture of the support is occluded and an unprotected zone wherein the microporous texture of the support is not occluded. Since Plouhar fails to disclose occluding any portion of the meshes microporous texture, Plouhar must also fail to disclose a mesh which includes a protected zone wherein a portion of the macroporous texture of the protected zone is

occluded and a portion of the macroporous texture of the protected zone is not occluded. Thus, Plouhar cannot possibly cure the deficiencies of Schmitt.

Scetbon fails to remedy the deficiencies of Schmitt and Plouhar. Nowhere does Scetbon disclose a textile support having a protected zone wherein the microporous texture of the support is occluded and an unprotected zone wherein the microporous texture of the support is not occluded. Rather, Scetbon, like Plouhar, discloses a mesh which includes a film without providing any further details regarding the microporous structure of the mesh. There is no disclosure of occluding the microporous texture in a protected zone and not occluding the microporous texture in a nonprotected zone in Scetbon. There is also no disclosure of occluding only a portion of the macropores in a protected zone (leaving other macropores of the protected zone un-occluded). Like Schmitt and Plouhar, therefore, Scetbon fails to disclose a textile support that has a protected zone wherein the microporous texture of the support is occluded and an unprotected zone wherein the microporous texture of the support is not occluded, wherein the protected zone includes a first portion where the macroporous texture is occluded and a second portion where the macroporous texture is not occluded. Thus, Scetbon cannot possibly cure the deficiencies of Schmitt and/or Plouhar.

Accordingly, withdrawal of the rejections regarding claims 1, 3-6, 8-10, 14, 15, and 24 as recited above is respectfully requested.

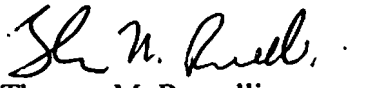
Claim 11 was also rejected under 35 U.S.C. §103(a) as being unpatentable over Schmitt in view of Plouhar, Scetbon and further in view of EP 0774240 A1 to Landgrebe et al. (hereinafter referred simply to as "Landgrebe"). Claim 11 depends from claim 1 and therefore includes all the limitations of claim 1. This rejection is respectfully traversed.

As noted above, neither Schmitt, Plouhar, nor Scetbon, taken alone or in any combination, render obvious claim 1 or any claim depending therefrom. Landgrebe does not, and is not cited in the office action as curing the above-noted deficiencies of Schmitt, Plouhar, and Scetbon. Rather, Landgrebe is cited for the shape of the implant. In fact, Landgrebe fails to disclose a textile support having a protected zone wherein the microporous texture of the support is occluded and an unprotected zone wherein the microporous texture of the support is not occluded, wherein the protected zone includes a first portion where the macroporous texture is occluded and a second portion where the macroporous texture is not occluded. Thus, Schmitt, Plouhar, Scetbon, and Landgrebe, taken alone or in any combination, fail to render claim 11 obvious and withdrawal of the rejection of claim 11 under 35 U.S.C. § 103(a) is respectfully requested.

Should the Examiner believe that a telephone interview may facilitate prosecution of this application, the Examiner is respectfully requested to telephone Applicant's undersigned representative at the number indicated above.

In view of the foregoing, this application is believed to be in condition for allowance. Such early and favorable action is earnestly solicited.

Respectfully submitted,



Thomas M. Rosselli
Reg. No. 53,532
Attorney for Applicant

Carter, DeLuca, Farrell & Schmidt, LLP
445 Broad Hollow Road, Suite 420
Melville, New York 11747
Tel.: (631) 501-5700
Fax: (631) 501-3526